JUL 1 1 2000

SURGIDEV® CORPORATION

K001234

510(k) Notification Summary

Contact Person: Margaret Aldred

Device Name: Bioinsulated® Silicone Punctum Plug

Device Common Name: Punctum Plug

Classification Name: Plug, punctum (86LZU)

Predicate Device: Surgidev® Silicone Punctum Plug

Device Description: A flexible silicone ophthalmic device designed to fit and be retained in the punctum.

Device Use: Used to enhance retention of eye fluids by occlusion of one or more puncta, reducing lacrimal flow. Useful for treatment of dry eye and other conditions where enhancement of tear retention is indicated.

Comparison to predicate device:

Features	Bioinsulated® Silicone Punctum Plug	Surgidev® Silicone Punctum Plug
Indications claimed	Treatment of dry eye after surgery. Treatment of ocular dryness secondary to contact lens use. Adjunctive treatment aid.	Treatment of dry eye after surgery. Treatment of ocular dryness secondary to contact lens use. Adjunctive treatment aid.
Function	Causes occlusion of the punctum, resulting in greater tear retention.	Causes occlusion of the punctum, resulting in greater tear retention.
Design: Length Diameter (typical)	1.7mm 0.5mm	1.7mm 0.5mm
Material	Medical grade silicone treated with polyvinylpyrrolidone	Medical grade silicone

Clinical tests: None

Adverse S & E Information None

MAldred

Margaret Aldred
Quality Assurance/Regulatory Affairs Manager

Date: 4/12/00

5743 Thornwood Drive • Goleta, California 93117 • Telephone: 805/683-3851 • Toll Free: 800/322-6976 in Ca / outside Ca: 800/235-5781

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1 2000

Surgidev Corporation
Margaret Aldred
5743 Thornwood Drive
Goleta, CA 93117

Re: K001234
Trade Name: Bioinsulated® Silicone Punctum Plug
Regulatory Class: Unclassified
Product Code: LZU
Dated: April 12, 2000
Received: April 17, 2000

Dear Ms. Aldred:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

ADDENDUM

Section G:

INDICATIONS (from labeling)

The Bioinsulated® Silicone Punctum Plug is intended for use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations which can be relieved by blockage of the punctum.

The Bioinsulated® Silicone Punctum Plug may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases such as corneal ulcers, conjunctivitis, pterygium, blepharitis, keratitis, red lid margins, recurrent chalazions, recurrent corneal erosion, filamentary keratitis and other external eye diseases.

When indicated, the Bioinsulated® Silicone Punctum Plug may be used after surgery of the eye to prevent complications due to dry eye and to enhance the retention of ocular medications. Patients experiencing ocular dryness secondary to contact lens use may also be aided by Bioinsulated® Silicone Punctum Plugs.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001234

Prescription Use ✓
(Per 21 CFR 801.109)